



#23/I.D.S.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Mar Tormo et al.

Serial No.: 09/381,747

Filed: September 22, 1999

For: INHIBITION OF BCL-2 PROTEIN  
EXPRESSION BY LIPOSOMAL  
ANTISENSE  
OLIGODEOXYNUCLEOTIDES

Group Art Unit: 1635

Examiner: Karen Lacourciere

Atty. Dkt. No.: UTSC:550

AUG 04 2004

TECHNICAL SERVICES

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U.S. PATENT & TRADEMARK OFFICE

CERTIFICATE OF MAILING  
37 C.F.R. 1.8

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July 28, 2004

Date

David L. Parker

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Supplemental Information Disclosure

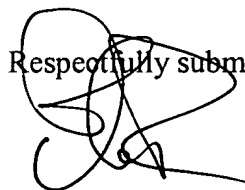
Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/UTSC:550.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



David L. Parker  
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Attorney for Applicants

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Date: July 28, 2004

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List of Patents and Publications for Applicant's

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## INFORMATION DISCLOSURE STATEMENT

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## U.S. Patent Documents

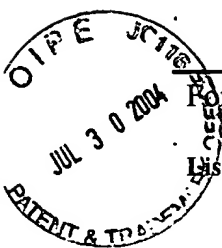
Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A42	4,480,041	10/30/84	Myles <i>et al.</i>	436	508	07-09-82
	A43	4,721,612	01/26/88	Janoff <i>et al.</i>	424	1.21	04-10-85
	A44	4,924,624	05/15/90	Suhadolnik <i>et al.</i>	514	44	10-22-87
	A45	4,950,432	08-21-90	Mehta <i>et al.</i>	264	4.6	10-16-87
	A46	5,015,568	05-14-91	Tsujimoto <i>et al.</i>	435	5	07-09-86
	A47	5,030,442	07/09/91	Uster <i>et al.</i>	424	45	04-04-89
	A48	5,049,388	09/17/91	Knight <i>et al.</i>	424	450	07-21-89
	A49	5,087,617	02/11/92	Smith	514	44	02-15-89
	A50	5,098,890	03/24/92	Gewirtz <i>et al.</i>	514	44	10-27-89
	A51	5,100,662	03/31/92	Bolcsak <i>et al.</i>	424	450	10-16-89
	A52	5,112,962	05/12/92	Letsinger <i>et al.</i>	536	25.3	11-09-90
	A53	5,135,917	08-04-92	Burch	514	44	07-12-90
	A54	5,178,875	01-12-93	Lenk <i>et al.</i>	424	450	01-14-91
	A55	5,227,170	07-13-93	Sullivan	424	450	06-20-90
	A56	5,248,671	09/28/93	Smith	514	44	12-09-91
	A57	5,264,618	11/23/93	Felgner <i>et al.</i>	560	224	04-16-91
	A58	5,271,941	12/21/93	Cho-Chung	424	450	05-20-91
	A59	5,279,957	01/18/94	Gross	435	348	04-30-92
	A60	5,320,962	06/14/94	Stiles <i>et al.</i>	435	252.3	07-22-92
	A61	5,324,654	06/28/94	Bredesen	435	376	02-08-92
	A62	5,459,251	10-17-95	Tsujimoto <i>et al.</i>	536	23.5	04-18-94
	A63	5,539,085	07-23-96	Bischoff <i>et al.</i>	530	350	08-20-93
	A64	5,539,094	07-23-96	Reed <i>et al.</i>	536	23.5	11-12-93

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	A65	5,560,923	10/01/96	Rahman <i>et al.</i>	424	450	09-28-94
	A66	5,565,337	10-15-96	Diamond <i>et al.</i>	435	70.2	08-23-94
	A67	5,622,852	04-22-97	Korsmeyer	435	325	10-31-94
	A68	5,756,122	05/26/98	Thierry <i>et al.</i>	424	450	07-07-95
	A69	5,817,811	10/06/98	Breipohl <i>et al.</i>	544	264	09-03-96
	A70	5,855,911	1/05/99	Lopez-Berestein and Tari	424	450	8/29/95
	A71	5,874,553	02/23/99	Peyman <i>et al.</i>	536	22.1	03-11-96

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	B6	0 252 685	1-13-88	Europe			English
	B7	CA 2,171,589	03/12/96	Canada			English
	B8	DE 4110085	03/27/91	Germany			Abstract
	B9	WO 89/06977	08/10/89	PCT			English
	B10	WO 90/09180	08/23/90	PCT			English
	B11	WO 90/10488	09/20/90	PCT			Abstract
	B12	WO 91/16901	11/14/91	PCT			English
	B13	WO 92/21330	12/10/92	PCT			Abstract
	B14	WO 93/07883	04/29/93	PCT			English
	B15	WO 93/11245	06/10/93	PCT			English
	B16	WO 93/24653	12-09-93	PCT			English
	B17	WO 94/04545	03/03/94	PCT			English
	B18	WO 94/05259	03/17/94	PCT			English

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	B19	WO 95/03788	02-09-95	PCT			English
	B20	WO 95/28497	10-26-95	PCT			English
	B21	WO 96/27663	09-12-96	PCT			
	B22	WO 96/40062	12/19/96	PCT			English

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	C5	Abubakr et al., "Effectiveness of Bcl-2 antisense oligodeoxynucleotides (AS-ODN) against human follicular small-cleaved cell lymphoma (FSCCL)-SCID mice xenograft model, <i>Blood</i> , 84 (10 Suppl. 1) 374A, 1994.
	C6	Agris et al., "Inhibition of vesicular stomatitis virus protein synthesis and infection by sequence-specific oligodeoxyribonucleoside methylphosphonates," <i>Biochemistry</i> , 25:6268-6275, 1986.
	C7	Akhtar et al., "Interactions of antisense DNA oligonucleotide analogs with phospholipid membranes (liposomes)," <i>Nucleic Acids Research</i> , 19(20): 5551-5559, 1991.
	C8	Akhtar et al., "Release of antisense oligodeoxynucleotide analogues from liposomes: implications for cellular transport and drug delivery," 128th Meeting of British Pharmaceutical Conference 1991, United Kingdom, September 10-13, 1991, <i>J. Pharm. Pharmacol.</i> , 43 (Suppl.):Abstract 24P, 1991.
	C9	Aktar et al., "Liposome Delivery of Antisense Methylphosphonate and Phosphorothioate Oligonucleotides: A Study with MLV, FATMLV, and LUV Liposomes," <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 19:345-346, 1992.
	C10	Allsopp et al., "The Proto-Oncogene bcl-2 Can Selectively Rescue Neurotrophic Factor-Dependent Neurons from Apoptosis," <i>Cell</i> , 73:295, 1993.
	C11	Arad et al., "Use of reconstituted sendai virus envelopes for fusion-mediated microinjection of double-stranded RNA: Inhibition of protein synthesis in interferon-treated cells," <i>Biochimica et Biophysica Acta</i> , 859:88-94, 1986.

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	C12	Bakhshi <i>et al.</i> , "Cloning the Chromosomal Breakpoint of t(14;18) Human Lymphomas: Clustering around J <sub>H</sub> on Chromosome 14 and near a Transcriptional Unit on 18," <i>Cell</i> , 41:899, 1985.
	C13	Bennett <i>et al.</i> , "Cationic lipids enhance cellular uptake and activity of phosphorothioate antisense oligonucleotides," <i>Molecular Pharmacology</i> , 41(6):1023-1033, 1992.
	C14	Boise, <i>et al.</i> , "bcl-x, a bcl-2-Related Gene That Functions as a Dominant Regulator of Apoptotic Cell Death", <i>Cell</i> , 74:597-608, 1993.
	C15	Boiziau <i>et al.</i> , "Modified oligonucleotides in rabbit reticulocytes: uptake, stability and antisense properties," <i>Biochimie</i> , 73:1403-1408, 1991.
	C16	Borzillo <i>et al.</i> , "Bcl-2 Confers Growth and Survival Advantage to Interleukin 7-dependent Early Pre-B Cells Which Become Factor Independent by a Multistep Process in Culture," <i>Oncogene</i> , 7:869, 1992.
	C17	Bradbury <i>et al.</i> , "Down-Regulation of bcl-2 in AML Blasts by All-Trans Retinoic Acid and Its Relationship of CD34 Antigen Expression," <i>British Journal of Haematology</i> , 94:671-675, 1996.
	C18	Budker <i>et al.</i> , "Cell membranes as barriers for antisense constructions," <i>Antisense Research and Development</i> , 2:177-184, 1992.
	C19	Campos <i>et al.</i> , "Effects of BCL-2 Antisense Oligodeoxynucleotides on In Vitro Proliferation and Survival of Normal Marrow Progenitors and Leukemic Cells," <i>Blood</i> , 84:595, 1994.
	C20	Capaccioli <i>et al.</i> , "Cationic lipids improve antisense oligonucleotide uptake and prevent degradation in cultured cells and in human serum," <i>Biochemical and Biophysical Research Communications</i> , 197(2):818-825, 1993.
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	C22	Cazals-Hatem <i>et al.</i> , "Molecular Cloning and DNA Sequence Analysis of cDNA Encoding Chicken Homologue of the Bcl-2 Oncoprotein," <i>Biochim. Biophys. Acta</i> , 1132:109, 1992.
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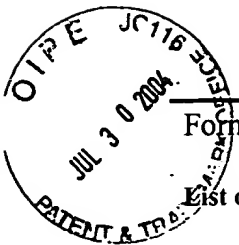
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	C24	Chen <i>et al.</i> , "Suppression of <i>Bcl-2</i> Messenger RNA Production May Mediate Apoptosis after Ionizing Radiation, Tumor Necrosis Factor $\alpha$ , and Ceramide," <i>Cancer Res.</i> , 55:991-994, 1995.
	C25	Cheng <i>et al.</i> , "Bax-independent inhibition of apoptosis by <i>Bcl-x<sub>L</sub></i> ," <i>Nature</i> , 279:554-556, 1996.
	C26	Chen-Levy and Cleary, "Membrane Topology of the <i>Bcl-2</i> Protooncogenic Protein Demonstrated <i>in Vitro</i> ," <i>J. Biol. Chem.</i> 265:4929, 1990.
	C27	Chen-Levy <i>et al.</i> , "The <i>bcl-2</i> Candidate Proto-Oncogene Product Is a 24-Kilodalton Integral-Membrane Protein Highly Expressed in Lymphoid Cell Lines and Lymphomas Carrying the t(14;18) Translocation," <i>Mol. Cell. Biol.</i> , 9:701, 1989.
	C28	Chittenden <i>et al.</i> , "Induction of apoptosis by the <i>Bcl-2</i> homologue Bak," <i>Nature</i> , 374:733, 1995.
	C29	Choi <i>et al.</i> , "The role of <i>bcl-X<sub>L</sub></i> in CD40-mediated rescue from anti- $\mu$ -induced apoptosis in WEHI-231 B lymphoma cells," <i>Eur. J. Immunol.</i> , 25:1352-1357, 1995.
	C30	Citro <i>et al.</i> , "Chemical modification of ligands for cell receptors to introduce foreign compounds into the cells," <i>Colon &amp; Rectum</i> , 37(2):S127-S132, 1994.
	C31	Clarenc <i>et al.</i> , "Delivery of Antisense Oligonucleotides by poly(L-Lysine) Conjugation and Liposome Encapsulation," <i>Anti-Cancer Drug Design</i> , 8:81-94, 1993.
	C32	Clarke <i>et al.</i> , "A recombinant <i>bcl-x<sub>S</sub></i> adenovirus selectively induces apoptosis in cancer cells but not in normal bone marrow cells," <i>Proc. Natl. Acad. Sci. USA</i> , 92:11024-11028, 1995.
	C33	Cleary <i>et al.</i> , "Cloning and Structural Analysis of cDNAs for <i>bcl-2</i> and a Hybrid <i>bcl-2</i> /Immunoglobulin Transcript Resulting from the t(14;18) Translation," <i>Cell</i> , 47:19, 1986.
	C34	Cotter <i>et al.</i> , "Antisense oligonucleotides suppress B-cell lymphoma growth in a SCID-hu mouse model," <i>Oncogene</i> , 9:304-3055, 1994.
	C35	Cuende <i>et al.</i> , "Programmed cell death by <i>bcl-2</i> -dependent and independent mechanisms in B lymphoma cells," <i>EMBO J.</i> , 12:1555-1560, 1993.
	C36	Datta <i>et al.</i> , "Overexpression of <i>Bcl-x<sub>L</sub></i> by Cytotoxic Drug Exposure Confers Resistance to Ionizing Radiation-induced Internucleosomal DNA Fragmentation," <i>Cell Growth &amp; Differentiation</i> , 6:363-370, 1995.
	C37	Dole <i>et al.</i> , " <i>Bcl-x<sub>L</sub></i> Is Expressed in Neuroblastoma Cells and Modulates Chemotherapy-Induced Apoptosis," <i>Cancer Res.</i> , 55:2576-2582, 1995.

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	C38	Duke <i>et al.</i> , "Morphological, biochemical and flow cytometric assays of apoptosis," <i>In: Coligan et al (eds) Current protocols in immunology</i> , vol 1., New York: John Wiley & sons, p 3.17.1, 1991.
	C39	Eguchi <i>et al.</i> , "Isolation and Characterization of the Chicken <i>bcl-2</i> Gene: Expression in a Variety of Tissues Including Lymphoid and Neuronal Organs in Adult and Embryo," <i>Nucl. Acids. Res.</i> , 20:4187, 1992.
	C40	Frankowski <i>et al.</i> , "Function and expression of the <i>Bcl-x</i> gene in the developing and adult nervous system," <i>NeuroReport</i> , 6:1917-1921, 1995.
	C41	Garcia <i>et al.</i> , "Prevention of Programmed Cell Death of Sympathetic Neurons by the <i>bcl-2</i> Prot-Oncogene," <i>Science</i> , 258:302, 1992.
	C42	Gerwitz <i>et al.</i> , "Facilitating oligonucleotide delivery: helping antisense delivery on its promise," <i>Proc. Natl. Acad. Sci U.S.A.</i> , 93: 3161-3163, 1996.
	C43	Gomez-Manzano <i>et al.</i> , "Bax, Bcl-2 and p53 Interactions Modulate p53-Induced Apoptosis in Glioma Cells," <i>Proceedings of the American Association for Cancer Research</i> , 37:204, Abstract 1397, March 1996.
	C44	González-García <i>et al.</i> , " <i>bcl-x</i> is expressed in embryonic and postnatal neural tissues and functions to prevent neuronal cell death," <i>Proc. Natl. Acad. Sci. USA.</i> , 92:4304-4308, 1995.
	C45	González-García <i>et al.</i> , " <i>bcl-x<sub>L</sub></i> is the major <i>bcl-x</i> mRNA form expressed during murine development and its product localizes to mitochondria," <i>Development</i> , 120:3033-3042, 1994.
	C46	Gottschalk <i>et al.</i> , "Identification of immunosuppressant-induced apoptosis in a murine B-cell line and its prevention by <i>bcl-x</i> but not <i>bcl-2</i> ," <i>Proc. Natl. Acad. Sci. USA.</i> , 91:7350-7354, 1994.
	C47	Gottschalk <i>et al.</i> , "The ability of Bcl- <i>x<sub>L</sub></i> and Bcl-2 to prevent apoptosis can be differentially regulated," <i>Death and Differentiation</i> , 3:113-118, 1996.
	C48	Graninger <i>et al.</i> , "Expression of <i>bcl-2</i> and <i>bcl-2</i> -Ig fusion transcripts in normal and neoplastic cells," <i>J. Clin. Invest.</i> , 80:1512, 1987.
	C49	Grever and Chabner, "Cancer Drug Discovery and Developoment," <i>Cancer Principles &amp; Practice of Oncology</i> , 5 <sup>th</sup> Edition, Lippicott-Raven Publishers, 19:385-394, 1997.
	C50	Grillot <i>et al.</i> , " <i>bcl-x</i> Exhibits Regulated Expression During B Cell Development and Activation and Modulates Lymphocyte Survival in Transgenic Mice," <i>J. Exp. Med.</i> , 183:381-391, 1996.

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	C52	Jäättelä <i>et al.</i> , "Bcl-x and Bcl-2 inhibit TNF and Fas-induced apoptosis and activation of phospholipase A <sub>2</sub> in breast carcinoma cells," <i>Oncogene</i> , 10:2297-2305, 1995.
	C53	Jasty <i>et al.</i> , " <i>bcl-x<sub>L</sub></i> , A Gene Which Regulates Programmed Cell Death, Is Expressed In Neuroblastoma Tumor Cell Lines (abstract)," <i>Clinical Res.</i> , 42:416A, 1994.
	C54	Juliano <i>et al.</i> , "Liposomes as a Drug Delivery System for Antisense Oligodeoxynucleotides Encapsulated by Liposomes," <i>Antisense Research and Development</i> , 2:165-176, 1992.
	C55	Kaneda <i>et al.</i> , "Increased Expression of DNA cointroduced with nuclear protein in adult rat liver," <i>Science</i> , 242:375-378, 1989.
	C56	Kato <i>et al.</i> , "Expression of hepatitis B virus surface antigen in adult rat liver," <i>J. Biol. Chem.</i> , 266:3361-3364, 1991.
	C57	Keller <i>et al.</i> , "Synthesis and hybridization properties of oligonucleotides containing 2'-O-modified ribonucleotides," <i>Nucleic Acids Research</i> , 21(19):4499-4505, 1993.
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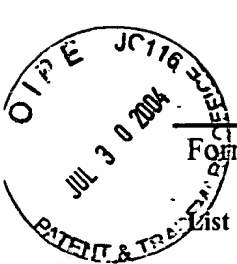
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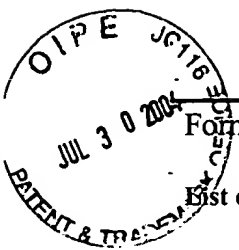
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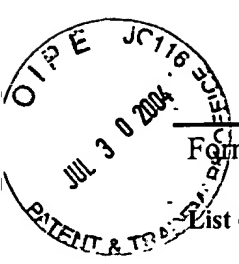
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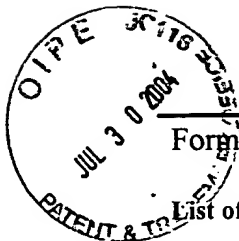
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